PCT/EP98/06065
17150P WO
Enclosure

Patent Claims

1. Liquid formulation which comprises human interferon-β as active ingredient in a concentration of up to 25 MU/ml and a buffer for setting a pH of 5 to 8, is free from human serum albumin and after storage for 3 months at 25°C shows a long-term stability of the biological in vitro activity of at least 80% of the initial activity, with the proviso that the formulation does not comprise any acidic amino acids, arginine or glycine in amounts of between 0.3 and 5% by weight.

3. Liquid formulation which comprises human inferferon-β as active ingredient, a buffer for setting a pH of 5 to 8, and one or more amino acids and shows after storage for 3 months at 25°C a long-term stability of the biological in vitro activity of at least 80% of the initial activity, with the proviso that the formulation does not comprise any acidic amino acids, arginine or glycine in amounts of between 0.3 and 5% by weight.

23. Pharmaceutical preparation according to Claim 21 or 22 in the form of unit doses of 1 to 25 MU.

25. Process for improving the shelf life of a liquid formulation which comprises human interferon-β as active ingredient and a buffer for setting a pH of 5 to 8,
characterized in that
a formulation without human serum albumin or/and with one or more amino acids is used, with the proviso that the formulation does not comprise any acidic amino acids, arginine or glycine in amounts of between 0.3 to 5% by weight.

26. Process according to Claim 25,
characterized in that
the improved shelf life encompasses improved long-term stability of the biological in vitro activity, of the chemical integrity or/and of the physical integrity.

vo - October 5, 1999

New Claim 2

2. Liquid formulation according to Claim 1, **characterized in that** it comprises a buffer for setting a pH of 6 to 7.2.